JUDGMENT OF THE COURT (Grand Chamber)

24 May 2005 *

In Case C-244/03,

ACTION for annulment under Article 230 EC, brought on 3 June 2003,

French Republic, represented initially by F. Alabrune, C. Lemaire and G. de Bergues, and subsequently by the latter and by J.-L. Florent and D. Petrausch, acting as Agents, with an address for service in Luxembourg,

applicant,

v

European Parliament, represented initially by J.L. Rufas Quintana and M. Moore, and subsequently by the latter and by K. Bradley, acting as Agents, with an address for service in Luxembourg,

* Language of the case: French.

and

Council of the European Union, represented by J.-P. Jacqué and M.C. Giorgi Fort, acting as Agents,

defendants,

THE COURT (Grand Chamber),

composed of V. Skouris, President, P. Jann and C.W.A. Timmermans, Presidents of Chambers, C. Gulmann, A. La Pergola, J.-P. Puissochet, R Schintgen, K. Schiemann (Rapporteur), J. Makarczyk, P. Kūris, U. Lõhmus, E. Levits and A. Ó Caoimh, Judges,

Advocate General: L.A. Geelhoed,
Registrar: K. Sztranc, Administrator,

having regard to the written procedure and further to the hearing on 18 January 2005,

after hearing the Opinion of the Advocate General at the sitting on 17 March 2005,

gives the following

Judgment

1 By its action, the French Republic is seeking the annulment of Article 1(2) of Directive 2003/15/EC of the European Parliament and of the Council of 27 February

2003 amending Council Directive 76/768/EEC on the approximation of the laws of the Member States relating to cosmetic products (OJ 2003 L 66, p. 26) in so far as that provision introduces an Article 4a into Directive 76/768 (hereinafter 'the contested provision').

2 Article 4a (hereinafter 'the provision in issue') is worded as follows:

'1. Without prejudice to the general obligations deriving from Article 2, Member States shall prohibit:

(a) the marketing of cosmetic products where the final formulation, in order to meet the requirements of this Directive, has been the subject of animal testing using a method other than an alternative method after such alternative method has been validated and adopted at Community level with due regard to the development of validation within the OECD;

(b) the marketing of cosmetic products containing ingredients or combinations of ingredients which, in order to meet the requirements of this Directive, have been the subject of animal testing using a method other than an alternative method after such alternative method has been validated and adopted at Community level with due regard to the development of validation within the OECD;

(c) the performance on their territory of animal testing of finished cosmetic products in order to meet the requirements of this Directive;

(d) the performance on their territory of animal testing of ingredients or combinations of ingredients in order to meet the requirements of this Directive, no later than the date on which such tests are required to be replaced by one or more validated alternative methods listed in Annex V to Council Directive 67/548/EEC of 27 June 1967 on the approximation of laws, regulations and administrative provisions relating to the classification, packaging and labelling of dangerous substances ... or in Annex IX to this Directive.

No later than 11 September 2004 the Commission shall, in accordance with the procedure referred to in Article 10(2) and after consultation of the Scientific Committee on Cosmetic Products and Non-Food Products intended for consumers (SCCNFP), establish the contents of Annex IX.

2. The Commission, after consultation of the SCCNFP and of the European Centre for the Validation of Alternative Methods (ECVAM) and with due regard to the development of validation within the OECD, shall establish timetables for the implementation of the provisions under paragraph 1(a), (b) and (d), including deadlines for the phasing-out of the various tests. The timetables shall be made available to the public not later than 11 September 2004 and be sent to the European Parliament and the Council. The period for implementation shall be limited to a maximum of six years after the entry into force of Directive 2003/15/EC in relation to paragraph 1(a), (b) and (d).

(2.1) In relation to the tests concerning repeated-dose toxicity, reproductive toxicity and toxicokinetics, for which there are no alternatives yet under consideration, the period for implementation of paragraph 1(a) and (b) shall be limited to a maximum of 10 years after the entry into force of Directive 2003/15/EC.

(2.2) The Commission shall study possible technical difficulties in complying with the ban in relation to tests, in particular those concerning repeated-dose toxicity, reproductive toxicity and toxicokinetics, for which there are no alternatives yet under consideration. Information about the provisional and final results of these studies should form part of the yearly reports presented pursuant to Article 9.

On the basis of these annual reports, the timetables established in accordance with paragraph 2 may be adapted within a maximum time-limit of six years as referred to in paragraph 2 or 10 years as referred to in paragraph 2.1 and after consultation of the entities referred to in paragraph 2.

(2.3) The Commission shall study progress and compliance with the deadlines as well as possible technical difficulties in complying with the ban. Information about the provisional and final results of the Commission studies should form part of the yearly reports presented pursuant to Article 9. If these studies conclude, at the latest two years prior to the end of the maximum period referred to in paragraph 2.1, that for technical reasons one or more tests referred to in paragraph 2.1 will not be developed and validated before the expiry of the period referred to in paragraph 2.1, it shall inform the European Parliament and the Council and shall put forward a legislative proposal in accordance with Article 251 of the Treaty.

(2.4) In exceptional circumstances where serious concerns arise as regards the safety of an existing cosmetic ingredient a Member State may request the Commission to grant a derogation from paragraph 1. The request shall contain an evaluation of the situation and indicate the measures necessary. On this basis, the Commission may, after consultation of the SCCNFP and by means of a reasoned decision, authorise the derogation in accordance with the procedure referred to in Article 10(2). This authorisation shall lay down the conditions associated with this derogation in terms of specific objectives, duration and reporting of the results.

A derogation shall only be granted if:

(a) the ingredient is in wide use and cannot be replaced by another ingredient able to perform a similar function;

(b) the specific human health problem is substantiated and the need to conduct animal tests is justified and is supported by a detailed research Protocol proposed as the basis for the evaluation.

...'

3 Article 1(1) of Directive 2003/15 provides for the deletion of Article 4(1)(i) of Directive 76/768. Article 4(1)(i), which was introduced into Directive 76/768 by

Council Directive 93/35/EEC of 14 June 1993 amending for the sixth time Directive 76/768 (OJ 1993 L 151, p. 32), provided as follows:

'Without prejudice to their general obligations deriving from Article 2, Member States shall prohibit the marketing of cosmetic products containing:

...

(i) ingredients or combinations of ingredients tested on animals after 1 January 1998 in order to meet the requirements of this Directive.

If there has been insufficient progress in developing satisfactory methods to replace animal testing, and in particular in those cases where alternative methods of testing, despite all reasonable endeavours, have not been scientifically validated as offering an equivalent level of protection for the consumer, taking into account OECD toxicity test guidelines, the Commission shall, by 1 January 1997, submit draft measures to postpone the date of implementation of this provision, for a sufficient period, and in any case for no less than two years, in accordance with the procedure laid down in Article 10. ...

...'

4 The date for the application of the latter provision was first deferred to 30 June 2000 and then to 30 June 2002 by Commission Directive 97/18/EC of 17 April 1997 (OJ 1997 L 114, p. 43) and Commission Directive 2000/41/EC of 19 June 2000 (OJ 2000 L 145, p. 25) respectively.

5 According to recital (18) in the preamble to Directive 2003/15, '[the] provisions of Directive 93/35/EEC banning the marketing of cosmetic products containing ingredients or combinations of ingredients tested on animals should be superseded by the provisions of this Directive. In the interests of legal certainty therefore it is appropriate to apply Article 1(1) of this Directive with effect from 1 July 2002, whilst fully respecting the principle of legitimate expectations'.

6 The second paragraph of Article 4 of Directive 2003/15 provides that Article 1(1) thereof is to apply from 1 July 2002.

The action

7 The French Republic relies on five pleas in support of its action. Primarily, it contends that the provision in issue infringes the principle of legal certainty. In the alternative, the French Republic submits that that provision interferes with the right freely to pursue a trade or profession and infringes the precautionary principle and the principles of proportionality and non-discrimination. It further requests that the defendants be ordered to pay the costs.

8 The Parliament and the Council contest both the admissibility and the merits of the action and submit that the action should be dismissed and the applicant ordered to pay the costs.

9 According to the Parliament, in so far as it provides in point (1) for the removal of the prohibition of marketing hitherto set out in Article 4(1)(i) of Directive 76/768 and in point (2) for the replacement of that prohibition by the system of prohibitions set out in the provision in issue, Article 1 of Directive 2003/15 forms a non-severable whole. To uphold the applicant's request for partial annulment would amount to legislating by judicial means. The Parliament points out in this regard that the part of Directive 2003/15 which deals with testing on animals was the result of an overall compromise reached within the conciliation committee at the conclusion of particularly difficult discussions involving the Council, the Commission and the Parliament. It is, the Parliament argues, obvious that, particularly in view of the legal context in which the contested provision features, Article 1(1) of Directive 2003/15 would never have been approved without the adoption at the same time of the provision in issue, with the result that those two provisions form a non-severable whole.

10 The Council pointed out during the hearing that it shared the view taken by the Parliament as to the impossibility of granting the partial annulment sought. Such an annulment, in the Council's view, would adversely affect the substance of Directive 2003/15 and the essential objectives pursued by the Community legislature by bringing about a system opposed in all respects to those objectives.

11 The French Government submits that the contested provision is severable from the other provisions of Directive 2003/15, which continue to produce legal effects. That is the case both with regard to the provisions of that directive concerning the safety of cosmetic products and consumer information and in respect of Article 1(1) of Directive 2003/15 providing for the deletion of Article 4(1)(i) of Directive 76/768 with effect from 30 June 2002.

12 It must be borne in mind in this regard that, as follows from settled case-law, partial annulment of a Community act is possible only if the elements the annulment of which is sought may be severed from the remainder of the act (see, inter alia, Case C-29/99 *Commission* v *Council* [2002] ECR I-11221, paragraphs 45 and 46; Case C-378/00 *Commission* v *Parliament and Council* [2003] ECR I-937, paragraph 30; and Case C-239/01 *Germany* v *Commission* [2003] ECR I-10333, paragraph 33).

13 Likewise, the Court has repeatedly ruled that that requirement of severability is not satisfied in the case where the partial annulment of an act would have the effect of altering its substance (Joined Cases C-68/94 and C-30/95 *France and Others* v *Commission* [1998] ECR I-1375, paragraph 257; *Commission* v *Council*, cited above, paragraph 46; and *Germany* v *Commission*, cited above, paragraph 34).

14 Admittedly, as the French Government points out, the Court has ruled, in regard to an implementing regulation adopted by the Commission, that the question whether partial annulment may alter the substance of the contested act is an objective criterion, and not a subjective criterion linked to the political intention of the authority which adopted the act at issue (*Germany* v *Commission*, cited above, paragraph 37).

15 In the present case, however, the unavoidable conclusion is that annulment of the contested provision, while Article 1(1) of Directive 2003/15 continues to apply, would objectively alter the very substance of the provisions adopted by the Community legislature in regard to testing on animals for the purpose of developing cosmetic products, as those provisions, moreover, constitute one of the principal axes of that directive.

16 The provision in issue, the grounds for the adoption of which are set out in the first 10 recitals in the preamble to Directive 2003/15, is, as becomes clear from recital (18) in that preamble, intended to 'supersede' Article 4(1)(i) of Directive 76/768.

17 As they have in part the same objective, that is to say, to set out in clearer terms the conditions governing the prohibition of marketing cosmetic products containing ingredients or combinations of ingredients that have been tested on animals, those two provisions, as the Parliament has correctly pointed out, could not have co-existed. The repeal of the former provision appears in this case as the consequence of the adoption of the new provision, a fact noted in recital (18) in the preamble to Directive 2003/15.

18 Furthermore, the connection between the provision in issue and that which it replaces is also emphasised by recital (4) in the preamble to Directive 2003/15, which states that '[in] accordance with Directive 86/609/EEC and with Directive 93/35/EEC, it is essential that the aim of abolishing animal experiments for testing cosmetic products be pursued and that the prohibition of such experiments becomes effective in the territory of the Member States'.

19 In those circumstances, the view must be taken that the inclusion of the provision in issue in Directive 76/768 and the deletion of Article 4(1)(i) of Directive 76/768 constitute a non-severable whole.

20 As the contested provision is thus non-severable from Article 1(1) of Directive 2003/15, it follows that the partial annulment requested by the applicant is impossible.

21 As the applicant has not requested, even by way of alternative submission, the annulment of Article 1(1), and as it, moreover, stressed in its reply and pointed out at the hearing that such a request by it would have been meaningless and that it was not seeking annulment of that provision, it must necessarily be held that the action is inadmissible (see the above judgments in *Commission* v *Council*, paragraphs 45 to 51, *Commission* v *Parliament and Council*, paragraphs 29 and 30, and *Germany* v *Commission*, paragraphs 33 to 38).

Costs

22 Under Article 69(2) of the Rules of Procedure, the unsuccessful party is to be ordered to pay the costs if they have been applied for in the successful party's pleadings. Since the Parliament and the Council have applied for costs to be awarded against the French Republic and the latter has been unsuccessful, the French Republic must be ordered to pay the costs.

On those grounds, the Court (Grand Chamber) hereby:

1. Dismisses the action;

2. Orders the French Republic to pay the costs.

[Signatures]